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2

☐ This application has been examined ☐ Responsive to communication filed on _____ ☐ This action is made final.

A shortened statutory period for response to this action is set to expire ten (10) month(s), thirty (30) days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- | | |
|---|---|
| 1. <input type="checkbox"/> Notice of References Cited by Examiner, PTO-892. | 2. <input type="checkbox"/> Notice re Patent Drawing, PTO-948. |
| 3. <input type="checkbox"/> Notice of Art Cited by Applicant, PTO-1449. | 4. <input type="checkbox"/> Notice of Informal Patent Application, Form PTO-152 |
| 5. <input type="checkbox"/> Information on How to Effect Drawing Changes, PTO-1474. | 6. <input type="checkbox"/> _____ |

Part II SUMMARY OF ACTION

1. ☒ Claims 1-84 are pending in the application.

Of the above, claims _____ are withdrawn from consideration.

2. ☐ Claims _____ have been cancelled.

3. ☐ Claims _____ are allowed.

4. ☐ Claims _____ are rejected.

5. ☐ Claims _____ are objected to.

6. ☒ Claims 1-84 are subject to restriction or election requirement.

7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.

8. ☐ Formal drawings are required in response to this Office action.

9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice re Patent Drawing, PTO-948).

10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____, has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).

11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).

12. ☐ Acknowledgement is made of the claim for priority under U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____; filed on _____.

13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.

14. ☐ Other

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-4, drawn to a composition for inducing the proliferation of a progenitor cell comprising a culture medium, classified in Class 435, subclass 240.2, for example.

II. Claims 5-16 and 79, drawn to a progenitor cell, classified in Class 435, subclass 240.1, for example.

This application contains claims directed to the following patentably distinct species of the claimed invention: Species A, claims 6, 8, 10; Species B, claims 7, 9, 11; Species C, claims 12-16. If Applicants elect Species C, claims 12 and 13 are generic and Applicants must further elect one of claims 14-16.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 5 and 79 are generic.

Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner
5 finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103 of the other invention.

III. Claims 17-21, drawn to a method for the in vitro proliferation of progenitor cells, classified in Class 435, subclass 240.21, for example.

10 This application contains claims directed to the following patentably distinct species of the claimed invention: Species A, claims 18 and 20; and Species B, claims 19 and 21.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted
15 if no generic claim is finally held to be allowable. Currently, claim 17 is generic.

Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any
20 claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent
25 form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner
5 finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103 of the other invention.

IV. Claims 22-26, drawn to a method for the in situ proliferation of progenitor cells wherein the cell is induced with a growth factor or
10 pharmaceutical composition, classified in Class 514, subclass 2, for example.

This application contains claims directed to the following patentably distinct species of the claimed invention: Species A, claims 23 and 24; Species B, claims 25 and 26. Applicants must elect one of Species A (a growth factor) and one of Species B (a method of delivery of the growth factor).

15 Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 22 is generic.

20 Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

25 Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as

provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103 of the other invention.

- 10 V. Claims 27-41, drawn to a method for the in vivo transplantation of progenitor cells, classified in Class 424, subclass 93U, for example.

This application contains claims directed to the following patentably distinct species of the claimed invention: Species A, claims 28, 33, 38; Species B, claims 30, 35, 40; Species C, claims 29, 34, 39; Species D, claims 31, 36 41.

- 15 Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 27, 32, 37 are generic.

- 20 Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

- 25 Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as

provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103 of the other invention.

- 10 VI. Claims 42-77, drawn to a method for treating neurological and neurodegenerative diseases comprising administering to a mammal in need of such a treatment a physiologically effective number of progenitor cells, classified in Class 424, subclass 93R, for example.

- 15 This application contains claims directed to the following patentably distinct species of the claimed invention: Species A, claims 43-46, 58-62, drawn to the type of donor; Species B, claims 47-57, 63, drawn to a neurologic disease or a neurodegenerative disease; Species C, claims 65-77, drawn to the particular site of administration. Applicants must elect from species A either the heterologous donor or the autologous donor and further, whether the donor is a fetus, juvenile or adult. Upon election of the subject matter, the appropriate claims will be examined. Note the incorrect claim dependencies. Applicants must further elect one claim from Species B, of claims 47-57, if claim 47 is elected claim 63 will also be examined. Applicants must elect one claim from Species C, specifying the location of the cells to be transplanted.

25 Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 42, 64 are generic.

Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all
5 claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as
10 provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly
15 admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103 of the other invention.

VII. Claim 78, drawn to a recombinant progenitor cell and the
20 neurotransplantation of the cells to treat neurodegenerative diseases, classified in Class 424, subclass 93B, for example.

VIII. Claims 80, 81, drawn to a method for the cryopreservation of progenitor cells, classified in Class 435, subclass 1, for example.

IX. Claim 82, drawn to the use of progenitor cells for the purposes of
25 drug screening of putative therapeutic agents, classified in Class 435, subclass 7.21, for example.

X. Claim 83, drawn to a method for the continuous perpetuation of progenitor cells in suspension culture, classified in Class 435, subclass 240.25, for example.

5 XI. Claim 84, drawn to a method for the continuous perpetuation of progenitor cells in substrate-attached cultures, classified in Class 435, subclass 240.23, for example.

The inventions are distinct, each from the other because of the following reasons:

10 Inventions II and Inventions (III-XI) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP 806.05(h)). In the instant case the product as claimed (the
15 progenitor cell) can be used in any of the materially different processes of Inventions III-XI.

Inventions I and II are independent and distinct inventions. Invention I, a composition comprising a culture medium, is useful for other processes such as the storage of progenitor cell or the cryopreservation of
20 progenitor cells or other cells. Invention II, the progenitor cell, can be cultured using other than the composition of claim 1.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, recognized divergent subject matter and separate search
25 requirements, restriction for examination purposes as indicated is proper.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

Serial No. 07/726,812

-9-

Art Unit 1804

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment
5 of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

Papers related to this application may be submitted to Group 180 by facsimile transmission. Papers should be faxed to Group 180 via the PTO Fax center located in Crystal Mall 1. The faxing of such papers must conform
10 with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703)308-4227.

An inquiry concerning this communication should be directed to Examiner Suzanne Ziska, Ph.D., at telephone number 703-308-3964.

Suzanne Ziska
Art Unit 1804
September 8, 1992